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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,936	11/21/2001	Kevin S. Brandt	FC-6-C4	7792
26949	7590	02/23/2004	EXAMINER	
HESKA CORPORATION INTELLECTUAL PROPERTY DEPT. 1613 PROSPECT PARKWAY FORT COLLINS, CO 80525			STRZELECKA, TERESA E	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/991,936

**Applicant(s)**

BRANDT ET AL.

**Examiner**

Teresa E Strzelecka

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27-38 is/are pending in the application.
- 4a) Of the above claim(s) 34-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-33, 37 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I (claims 27-33, 37, 38, 46 and 47, SEQ ID NO: 1875) in Paper No. 17112003 is acknowledged. The traversal is on the ground(s) that a) sequences with SEQ ID NO: 1872-1876 should be prosecuted together, since SEQ ID NOs 1872 and 1875 are cDNAs encoding a protein with amino acid sequence of SEQ ID NO: 1873, and SEQ ID NOs 1874 and 1876 are complementary to SEQ ID NOs 1872 and 1875, b) examination of the nucleic acid and a method of producing a protein using a nucleic acid does not constitute an undue burden.

Regarding a), SEQ ID NOs 1872, 1874-1876 will be examined together, however, SEQ ID NO: 1873, which is an amino acid sequence, will not. Examination of an amino acid sequence requires a separate search, different from the search for the nucleic acids, adding search burden to the examiner and sequence search services at USPTO.

Regarding b), the product claims, 27-33, 37, 38, 46 and 47, are drawn to nucleic acids hybridizing with nucleic acids of SEQ ID NOs 1872, 1874-1876 under low stringency conditions. Therefore, there are potentially a large number of nucleic acids fulfilling this requirement, and, therefore, searching for methods of protein production using each one of those nucleic acids adds a serious burden to the examination.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 34-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 17112003.

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3. Applicants cancelled claims 1-26 and 39-47. Claims 27-38 are pending, with claims 34-36 withdrawn from consideration. Claims 27-33, 37 and 38 will be examined to the degree that they read on SEQ ID NOs 1872 and 1874-1876.

4. Applicants' petition to correct inventorship under 37 CFR 1.48(b) has been approved and a copy is provided for Applicants with this office action.

***Information Disclosure Statement***

5. The information disclosure statement filed November 21, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

***Priority***

6. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 27-33, 37 and 38 of this application. The provisional application 60/128,704 lists SEQ ID NOs 1-1363 only, therefore claims 27-33, 37 and 38, which are drawn to nucleic acids with SEQ ID NO: 1872 and 1874-1876 have a priority date of the application 09/543,668, April 7, 2000.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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8. Claims 27-33, 37 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of nucleic acids which are different from those disclosed in the specification. The genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named SEQ ID NOs: 1872 and 1874-1876. Thus, applicant has express possession of only three particular nucleic acids which hybridize to SEQ ID NO: 1872, for example, in a genus which comprises hundreds of millions of different possibilities. Further, these claims encompass alternately spliced versions of the proteins, allelic variants including insertions and mutations, inactive precursor proteins which have a removable amino terminal end, and only specific amino acid sequences have been provided. No written description of alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

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Even though there is a functional limitation of the nucleic acids having a chloride channel activity, Applicants did not show that SEQ ID NOs: 1872 and 1874-1876 encode a chloride channel. On page 202 of the specification, Applicants assert that SEQ ID NO: 1872 has 37.5 % identity with Homo sapiens chloride intracellular channel 2 (Accession No. NM001289). However, the sequence search performed at USPTO did not confirm this result. Further, the sequence search revealed that SEQ ID NO: 1875 is 52.5% identical over 236 bp (443-678) to laminin (Accession No. ABZ25018/c) and 52.5% identical over the same 236 bp (443-678) to a human ion channel (Accession No. AAD27280) (see sequence alignment). Therefore, since these two sequence alignment point to two entirely different classes of proteins, it is not clear that any of the SEQ ID NO: 1872 or 1875 encode a chloride channel.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

"A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of the nucleic acids hybridizing to SEQ ID NO: 1872, for example, lack any specific structure, is precisely the situation of naming a type of material which is generally known to likely exist, but, except for the four specific sequences, is in the absence of knowledge of the material composition and fails to provide descriptive support for the

generic claim to "a nucleic acid molecule that hybridizes to a polynucleotide selected from the group consisting of SEQ ID NO: 1874 or 1876", for example.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound solely but its functional utility, as nucleic acid hybridizing to SEQ ID NO: 1872, without any definition of the particular sequences claimed.

In the instant application, certain specific SEQ ID NOs are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which comprise SEQ ID NO: 1872 and 1874-1876. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

### *Claim Rejections - 35 USC § 101*

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 27-33, 37 and 38 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The current claims are drawn to a genus of *C. felis* nucleic acids hybridizing under low stringency conditions to SEQ ID NO: 1872 and 1874-1876, which nucleic acids encode chloride channels.

### **Credible Utility**

Following the requirements of the Utility Guidelines (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.), the first inquiry is whether a credible utility is cited in the specification for use of the nucleic acids. The only cited utilities identified by the examiner are to detect other nucleic acid molecules (page 125, lines 12-22), preparation of oligonucleotides capable of hybridization to the nucleic acids, acting as probes, primers or antisense molecules (page 126, lines 7-20), preparation of recombinant vectors for expression of polypeptides (page 127, lines 3-22) and vaccines (page 148). These utilities are credible.

Upon identification of credible utilities, the next issue is whether there are any well established utilities for the protein. No well established utilities for these specific nucleic acids are identified the specification.

### **Substantial utility**

Given the absence of a well established utility, the next issue is whether substantial utilities are disclosed in the specification. Here, the only evidence provided by Applicants is an assertion on page 202 of the specification that SEQ ID NO: 1872 has 37.5 % identity with Homo sapiens chloride intracellular channel 2 (Accession No. NM001289). However, the sequence search performed at USPTO did not confirm this result. Further, the sequence search revealed that SEQ ID NO: 1875 is 52.5% identical over 236 bp (443-678) to laminin (Accession No. ABZ25018/c) and 52.5% identical over the same 236 bp (443-678) to a human ion channel (Accession No.



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AAD27280) (see sequence alignment). Therefore, since these two sequence alignment point to two entirely different classes of proteins, it is not clear that any of the SEQ ID NO: 1872 or 1875 encode a chloride channel.

Applicants assert in the specification that the nucleic acids encoding chloride channels can be used as targets for anti-flea vaccines and drugs (page 15, lines 8-11). However, Applicants state "If the CLIC gene product is indeed involved in transepithelial chloride transport in HMT tissues..." (page 15, lines 8 and 9), further confirming that Applicants did not know the function of a protein encoded by SEQ ID NO: 1872 or 1875.

#### **Specific Utility**

The claimed nucleic acid compounds are not supported by a specific utility because the disclosed uses of the nucleic acids are not specific and are generally applicable to any nucleic acid. The specification states that the nucleic acid compounds may be useful to detect other nucleic acid molecules (page 125, lines 12-22), preparation of oligonucleotides capable of hybridization to the nucleic acids, acting as probes, primers or antisense molecules (page 126, lines 7-20), preparation of recombinant vectors for expression of polypeptides (page 127, lines 3-22) and vaccines (page 148). These are non-specific uses that are applicable to nucleic acids and proteins in general and not particular or specific to the nucleic acids and proteins being claimed.

11. No claims are allowed.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

